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LEGISLATIVE INSTRUCTOR

January 15, 2014

Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

RE: Proposed Regulations Governing Cardiac Services

Dear Mr. Steffen:

As members of the Prince George's Delegation of the Maryland General Assembly, we are each keenly focused on the status of health care of the citizens in our county and on the resources available to improve access to care and the health outcomes of the people we represent. We have collaborated for years to improve and transform the delivery of health care services in the county, including those at the Prince George's Hospital Center, and we are monitoring closely all of the plans to develop a new, comprehensive regional medical center.

Far too many of our constituents travel outside of the county to seek a variety of services which can and should be provided in Prince George's County. Consequently, some of the services provided in-county, like cardiac services, are lower volume services. We look forward to seeing that out-migration reversed and we will work hard to make that feasible.

With these concerns in mind, we have reviewed and discussed the proposed regulations regarding cardiac services pending review in the legislature. There are multiple issues in the proposed regulations which we find troublesome and believe must be addressed:

- **Voluntary Relinquishment**

As currently proposed, every hospital would be required to agree to voluntarily relinquish its authority to operate a cardiac service program as a pre-condition to

starting the program or continuing its operation. The legislation enacted by the legislature two years ago referred to revocation of a cardiac service Certificate of Need. There is no legal authority that would permit the Maryland Health Care Commission (MHCC) to require a hospital to agree to "voluntarily relinquish" its authority to operate cardiac services as a pre-requisite to establishing or maintaining the program(s). "Voluntary relinquishment" and "revocation" are two distinct procedures, with distinct implications, remedies and appeal rights should a hospital dispute the commission's directive to close a cardiac service. "Voluntary relinquishment", as a pre-condition severely impinges those rights. This pre-condition requirement should be stricken entirely.

- **Focused Review for Surgery Volume Below 100 Cases Annually**

The proposed regulations (now) provide for a focused review of a hospital with a cardiac surgery case volume below 100 cases annually. Under the proposed regulations, a hospital could submit a plan of correction; however, it is clear that the commission may reject that plan or determine, in reasonably short order, that any perceived deficiencies have not been addressed. Should that occur, the commission has the right to ask that the hospital voluntarily relinquish its CON or Certificate of On-going Performance pursuant to the (pre-condition) agreement and the program would be closed. Cardiac surgery programs should more appropriately be evaluated over a two year period, as proposed in the informal proposed regulations set out in the Fall of 2013. Program fluctuations are more likely to regulate over a two year period.

- **Automatic Program Closure**

No cardiac service should be closed automatically, after any period of review. As the Clinical Advisory Committee discussed, volume and quality should be discussed in tandem and a program should be "considered" for closure under certain circumstances, e.g. volume below 100 cases for two consecutive years or a one star STS rating for four consecutive six month periods. These proposed regulations provide for automatic closure of a cardiac surgery program with a one star rating for effectively two years, without further discussion or review. Indeed, there may be mitigating factors that contribute to the low volume and again volume alone is not determinative of quality.

- **Prospective Versus Retrospective Program Review**

Any program evaluation should be prospective. There are a series of new requirements in the regulations and each program should have an opportunity to meet them before any program sanctions are meted out. Indeed, Prince George's Hospital Center does not currently participate in the STS database and would need grace time to come within that rubric.

- **Cardiac Surgery Planning Regions and Impact on Programs Within, or in Adjacent, Regions**

The four counties on the Upper Eastern Shore should not be consolidated with the Baltimore Metropolitan region. The planning regions for cardiac surgery should remain consistent with the planning regions for every other service governed by the MHCC. Patients on the Eastern Shore are prime patients to travel Route 50 and receive care at Prince George's Hospital Center and the new replacement facility. Moreover, modification of the planning regions just after the new Medicare Waiver has been approved seems precipitous. Global budgeting under the new plan will force an examination of volume changes and market share assumptions. We agree and find this unacceptable with respect to Prince George's County. Finally, the regulations should require any hospital seeking a new CON for cardiac services to consider the impact of its proposed program on any program in its service area and adjacent service areas, without regard to a threshold minimum case volume of 100 cases.

The Delegation strongly urges due and appropriate consideration of the issues raised in this letter. The impact of the proposed regulations on Prince George's Hospital Center and the citizens of Prince George's County is substantial, to say the least. We are concerned that as the regulations are currently drafted, Prince George's County could lose its one and only cardiac surgery and angioplasty program, just at the time when substantial investments are being made by the State and the County to improve access to care in this jurisdiction and the southern Maryland region.

As you know, as part of this healthcare investment strategy, Dimensions Health System has embarked on a plan with the University of Maryland Medical System to strengthen the care delivered at Prince George's Hospital, including cardiac services. These regulations, as currently drafted, would preclude that program development from coming to fruition.

Finally, Prince George's Hospital houses the second busiest trauma center in the State. We are advised by the hospital's Chief Medical Officer and former director of the trauma center that maintaining the trauma program without cardiac surgery on site is unthinkable.

Accordingly, we offer a few recommendations/solutions for the MHCC, which are not mutually exclusive:

Delay the effective date of the cardiac surgery sections of the proposed regulations until September 2015, until the implications of the new Waiver and market share analyses are more clear.

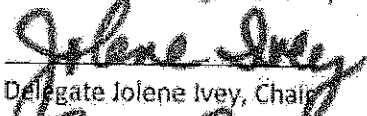
- 1- Provide a mechanism to recognize the importance of a cardiac surgery program to a robust trauma center, like the one at Prince George's Hospital, and preserve the operation of the program at PGHC.

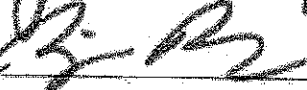
- 2- Provide a mechanism to recognize the importance of a cardiac surgery program to a robust trauma center, like the one at Prince George's Hospital, and preserve the operation of the program at PGHC.
- 3- Provide an appropriate and adequate response time for program development given the unique circumstance involving Prince George's Hospital and the University of Maryland Medical System.
- 4- Retract/modify the cardiac surgery provisions, including especially the prospective application of any and all standards of review over a two year course of time and maintaining the current health service planning regions.

We stand ready to work with you to achieve the best results for Prince George's County and look forward to your reply.

Sincerely,

The Prince George's County House Delegation:


Delegate Jolene Ivey, Chair


Delegate Ben Barnes, Vice


Chair


Delegate Veronica Turner,

2nd Vice Chair

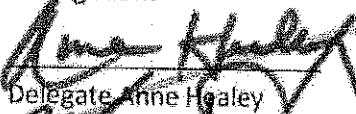

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